HIPAA PRIVACY REGULATIONS EXTRACT OF PREEMPTION REFERENCES

(64 Fed.Reg. 59918 *et seq*. (Nov. 3, 1999))

Prepared by:
Stephen A. Stuart, Senior Staff Counsel
California Office of HIPAA Implementation
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EXPLANATION

The following document is a tool designed to assist HIPAA-covered persons and entities in analyzing provisions of State law for preemption by the Health Insurance Portability and Accountability Act (HIPAA). The document is an extract of all references to HIPAA preemption of State law set forth in the Proposed Rule: Standards for Privacy of Individually Identifiable Health Information (NPRM) on November 3, 1999. (64 Fed.Reg. 59918 et seq. (Nov. 3, 1999).)

Please forward any comments, corrections, etc. to the attention of:

Stephen A. Stuart
Senior Staff Counsel
California Office of HIPAA Implementation
1600 Ninth Street, Room 400
Sacramento, CA 95814
(916) 651-6908
sstuart1@ohi.ca.gov

HIPAA Privacy Regulations
Extract of Preemption References
(64 Fed.Reg. 59918 *et seq*. (Nov. 27, 1999))

I. Background

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B. Statutory Background

Under section 1178 of the Act, the requirements of part C, as well as any standards or implementation specifications adopted thereunder, preempt contrary State law. There are three exceptions to this general rule of preemption: State laws that the Secretary determines are necessary for certain purposes set forth in the statute; State laws that the Secretary determines address controlled substances; and State laws relating to the privacy of individually identifiable health information that are contrary to and more stringent than the federal requirements. There also are certain areas of State law (generally relating to public health and oversight of health plans) that are explicitly carved out of the general rule of preemption and addressed separately.

Section 1179 of the Act makes the above provisions inapplicable to financial institutions or anyone acting on behalf of a financial institution when ''authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for a financial institution.'' Finally, as explained above, section 264 requires the Secretary to issue standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a)(1). Section 264 also contains a preemption provision that provides that contrary provisions of State laws that are more stringent than the federal standards, requirements, or implementation specifications will not be preempted. [59922 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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E. Summary and Purpose of the Proposed Rule

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9. Preemption

The HIPAA provides that the rule promulgated by the Secretary may not preempt state laws that are in conflict with the regulatory requirements and that provide greater privacy protections. The HIPAA also provides that standards issued by the Secretary will not supercede certain other State laws, including: State laws relating to reporting of disease or injury, child abuse, birth or death, public health

surveillance, or public health investigation or intervention; State regulatory reporting; State laws which the Secretary finds are necessary to prevent fraud and abuse, to ensure appropriate State regulation of insurance, for State reporting on health care delivery or costs, or for other purposes; or, State laws which the Secretary finds address controlled substances. These provisions are discussed in more detail in preamble section II.I.1. This proposed rule also must be read in conjunction with other federal laws and regulations that address the use and disclosure of health information. These issues are discussed in preamble section II.I.2. In general, the rule that we are proposing would create a federal floor of privacy protection, but would not supercede other applicable law that provide greater protection to the confidentiality of health information. In general, our rule would not make entities subject to a state laws to which they are not subject today. [59926 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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II. Provisions of the Proposed Rule

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A. Applicability

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4. References to Other Laws

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Where particular types of law are at issue, such as in the proposed provisions for preemption of State law in subpart B of part 160…we so indicate by referring to the particular type of law in question (e.g., "state law" or "federal law"). [59929 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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B. Definitions

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18. Individual

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c. Disclosures Pertaining to Minors

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Laws regarding access to health care for minors and confidentiality of their medical records vary widely; this proposed regulation recognizes and respects the current diversity of the law in this area. It would not affect applicable regulation of the delivery of health care services to minors, and would not preempt any law authorizing or prohibiting disclosure of individually identifiable health information of minor individuals to their parents. The disclosure of individually identifiable health information from substance abuse records is also addressed by additional requirements established under 42 CFR part 2. [59935

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22. Protected Health Information

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Individually identifiable health information that is part of an ''education record'' governed by the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g, would not be considered protected health information. Congress specifically addressed such information when it enacted FERPA to protect the privacy rights of students and parents in educational settings. FERPA applies to educational records that are maintained by educational agencies and institutions that are recipients of federal funds from the Department of Education. FERPA requires written consent of the parent or student prior to disclosure of education records except in statutorily specified circumstances. We do not believe that Congress intended to amend or preempt FERPA in enacting HIPAA. [59938 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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C. General Rules (§ 164.506)

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The proposed rule generally would not require covered entities to vary the level of protection of protected health information based on the sensitivity of such information. We believe that all protected health information should have effective protection from inappropriate use and disclosure by covered entities, and except for limited classes of information that are not needed for treatment and payment purposes, we have not provided additional protection to protected health information that might be considered particularly sensitive. We would note that the proposed rule would not preempt provisions of other applicable laws that provide additional privacy protection to certain classes of protected health information. [59938 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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E. Uses and Disclosures Permitted Without Individual Authorization (§ 164.510)

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1. Uses and Disclosures for Public Health Activities (§ 164.510(b))

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We also note that the preemption provision of the HIPAA statute creates a special rule for a subset of public health disclosures: this regulation cannot preempt State law regarding ''public health surveillance, or public health investigation or intervention. [59957 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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3. Use and Disclosure for Judicial and Administrative Proceedings (§ 164.510(d))
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We note that there are other existing legal requirements governing the disclosure of protected health information, and which govern the procedures in federal, State and other judicial and administrative proceedings. For example, 42 U.S.C. 290dd–2 and the implementing regulations, 42 CFR part 2, will continue to govern the disclosure of substance abuse patient records. There may also be provisions of a particular State's law governing State judicial or administrative proceedings, including State medical record privacy statutes, as well as precedential court opinions, which apply to the circumstances described in the section, that will not be preempted by this part. Also, the discovery of psychiatric counseling records in federal proceedings governed by section 501 of the Federal Rules of Evidence, has been restricted in certain circumstances, by *Jaffee* v. *Redmond,* 116 S. Ct. 1923 (1996). These more stringent rules would remain in place. [59959 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]
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5. Disclosure for Law Enforcement (§ 164.510(f))
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In obtaining protected health information, law enforcement officials would have to comply with whatever other law was applicable. In certain circumstances, while this subsection could authorize a covered entity to disclose protected health information to law enforcement officials, there could be additional applicable statutes that further govern the specific disclosure. If the preemption provisions of this regulation do not apply, the covered entity must comply with the requirements or limitations established by such other law, regulation or judicial precedent. See proposed §§ 160.201 through 160.204. For example, if State law would permit disclosure only after compulsory process with court review, a provider or payer would not be allowed to disclose information to state law enforcement officials unless the officials had complied with that requirement. Similarly, disclosure of substance abuse patient records subject to, 42 U.S.C. 290dd–2, and the implementing regulations, 42 CFR part 2, would continue to be governed by those provisions. [59963 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]
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6. Uses and Disclosures for Governmental Health Data Systems (§ 164.510(g))
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We considered whether to allow disclosure by all covered entities to governmental data collection systems or to limit permitted disclosures to those made by health plans, as specified in the regulatory reporting provision of HIPAA. While this provision only mentions data collected from health plans, the conference agreement notes that laws regarding ''State reporting on health care

delivery or costs, or for other purposes'' should not be preempted by this rule. States would be likely to require sources of information other than health plans, such as health care providers or clearinghouses, in order to examine health care delivery or costs. Therefore, we do not believe it is appropriate to restrict States' or other governmental agencies' ability to obtain such data. This viewpoint is consistent with the Recommendations, which would permit this disclosure of protected health information by all covered entities. [59965 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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I. Relationship to Other Laws

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1. Relationship to State Laws

Congress addressed the issue of preemption of State law explicitly in the statute, in section 1178 of the Act. Consonant with the underlying statutory purpose to simplify the financial and administrative transactions associated with the provision of health care, the new section 1178(a)(1) sets out a ''general rule'' that State law provisions that are contrary to the provisions or requirements of part C of title XI or the standards or implementation specifications adopted or established thereunder are preempted by the federal requirements. The statute provides three exceptions to this general rule: (1) For State laws which the Secretary determines are necessary to prevent fraud and abuse, ensure appropriate State regulation of insurance and health plans, for State reporting on health care delivery, and other purposes; (2) for State laws which address controlled substances; and (3) for State laws relating to the privacy of individually identifiable health information which, as provided for by the related provision of section 264(c)(2), are contrary to and more stringent than the federal requirements. Section 1178 also carves out, in sections 1178(b) and 1178(c), certain areas of State authority which are not limited or invalidated by the provisions of part C of title XI; these areas relate to public health and State regulation of health plans.

Section 264 of HIPAA contains a related preemption provision. Section 264(c)(2) is, as discussed above, an exception to the ''general rule'' that the federal standards and requirements preempt contrary State law. Section 264(c)(2) provides, instead, that contrary State laws that relate to the privacy of individually identifiable health information will not be preempted by the federal requirements, if they are ''more stringent'' than those requirements. This policy, under which the federal privacy protections act as a floor, but not a ceiling on, privacy protections, is consistent with the Secretary's Recommendations.

Aside from the cross-reference to section 264(c)(2) in section 1178(a)(2)(B), several provisions of section 1178 relate to the proposed privacy standards. These include the general preemption rule of section 1178(a)(1), the carve-out for public health and related reporting under section 1178(b), and the carve-out for reporting and access to records for the regulation of health plans by States under section 1178(c). Other terms that occur in section 264(c)(2) also appear in section 1178: The underlying test for preemption—whether a State law is ''contrary'' to the federal standards, requirements or implementation specifications—appears throughout section 1178(a), while the issue of what is a ''State law'' for preemption purposes applies throughout section 1178. In light of these factors, it seems logical to develop a regulatory framework that addresses the various issues raised by section 1178, not just those parts of it implicated by section 264(c)(2). Accordingly, the rules proposed below propose regulatory provisions covering these issues as part of the general provisions in proposed part 160, with sections made specifically applicable to the proposed privacy standard where appropriate.

a. The ''general rule'' of preemption of State law

Section 1178(a)(1) provides the following ''general rule'' for the preemption of State law:

> Except as provided in paragraph (2), a provision or requirement under this part (part C of title XI), or a standard or implementation specification adopted or established under sections 1172 through 1174, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

As we read this provision, the provisions and requirements of part C of [59995 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules] title XI, along with the standards and implementation specifications adopted thereunder, do not supplant State law, except to the extent such State law is ''contrary'' to the federal statutory or regulatory scheme. Moreover, the provisions and requirements of part C of title XI, along with the standards and implementation specifications adopted thereunder, do not preempt contrary State law where one of the exceptions provided for by section 1178(a)(2) applies or the law in question lies within the scope of the carve-outs made by sections 1178(b) and (c). Thus, States may continue to regulate in the area covered by part C of title XI and the regulations and implementation specifications adopted or established thereunder, except to the extent States adopt laws that are contrary

to the federal statutory and regulatory scheme, and even those contrary State laws may continue to be enforceable, if they come within the statutory exceptions or carveouts.

We note, however, that many of the Administrative Simplifications regulations will have preemptive effect. The structure of many of the regulations, particularly those addressing the various administrative transactions, is to prescribe the use of a particular form or format for the transaction in question. Where the prescribed form or format is used, covered entities are required to accept the transaction. A State may well not be able to require additional requirements for such transactions consistent with the federally prescribed form or format.

b. Exceptions for State laws the Secretary determines necessary for certain purposes.

Section 1178(a)(2) lists several exceptions to the general preemption rule of section 1178(a)(1). The first set of exceptions are those listed at sections 1178(a)(2)(A)(i) and 1178(a)(2)(A)(ii). These exceptions are for provisions of State law which the Secretary determines are necessary: (1) To prevent fraud and abuse; (2) to ensure appropriate State regulation of insurance and health plans; (3) for State reporting on health care delivery or costs; (4) for other purposes; or (5) which address controlled substances.

Proposed § 160.203(a) below provides for determinations under these statutory provisions. The criteria at proposed § 160.203(a) follow the statute. As is more fully discussed below, however, two of the terms used in this section of the proposed rules are defined terms: ''contrary'' and ''State law.'' The process for making such determinations is discussed below.

c. Exceptions for State laws relating to the privacy of individually identifiable health information.

The third exception to the ''general rule'' that the federal requirements, standards, and implementation specifications preempt contrary State law concerns State laws relating to the privacy of individually identifiable health information. Section 1178(a)(2)(B) provides that a State law is excepted from this general rule, which, ''subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.'' Section 264(c)(2) of HIPAA provides that the HIPAA privacy regulation, which is proposed in the accompanying proposed subpart B of proposed part 160, will not supersede ''a contrary provision of State law, if the provision of State law imposes requirements, standards, or

implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed'' under the regulation at proposed subpart E of proposed part 164.

It is recognized that States generally have laws that relate to the privacy of individually identifiable health information. These laws continue to be enforceable, unless they are contrary to part C of title XI or the standards, requirements, or implementation specifications adopted or established pursuant to the proposed subpart x. Under section 264(c)(2), not all contrary provisions of State privacy laws are preempted; rather, the law provides that contrary provisions that are also ''more stringent'' than the federal regulatory requirements or implementation specifications will continue to be enforceable.

d. Definitions.

There are a number of ambiguities in sections 1178(a)(2)(B) and 264(c)(2) of HIPAA. Clarifying the statute through the regulations will generally provide substantially more guidance to the regulated entities and the public as to which requirements, standards, and implementation specifications apply. For these reasons, the rules propose below to interpret several ambiguous statutory terms by regulation.

There are five definitional questions that arise in considering whether or not a State law is preempted under section 264(c)(2): (1) What is a ''provision'' of State law? (2) What is a ''State law''? (3) What kind of State law, under section 1178(a)(2)(B), ''relates to the privacy of individually identifiable health information?'' (4) When is a provision of State law at issue ''contrary'' to the analogous provision of the federal regulations? (5) When is a provision of State law ''more stringent than'' the analogous provision of the federal regulations? We discuss these questions and our proposed regulatory answers below.

i. What is a ''provision'' of State law?

The initial question that arises in the preemption analysis is, what does one compare? The statute directs this analysis by requiring the comparison of a ''provision of State law [that] imposes requirements, standards, or implementations specifications'' with ''the requirements, standards, or implementation specifications imposed under'' the federal regulation. The statute thus appears to contemplate that what will be compared are the State and federal requirements that are analogous, i.e., that address the same subject matter. Accordingly, a dictionary-type definition of the term ''provision'' does not seem appropriate, as the contours of a given ''provision'' will be largely defined

by the contours of the specific ''requirement[], standard[], or implementation specification'' at issue.

What does one do when there is a State provision and no comparable or analogous federal provision, or the converse is the case? The short answer would seem to be that, since there is nothing to compare, there cannot be an issue of a ''contrary'' requirement, and so the preemption issue is not presented. Rather, the stand-alone requirement—be it State or federal—is effective. There may, however, be situations in which there is a federal requirement with no directly analogous State requirement, but where several State requirements in combination would seem to be contrary in effect to the federal requirement. This situation usually will be addressed through the tests for ''contrary,'' discussed below.

At this juncture, it is difficult to frame options for dealing with this issue, because it is not clear that more of a structure is needed than the statute already provides. Rather, we solicit comment on how the term ''provision'' might be best defined for the purpose of the preemption analysis under the statute, along with examples of possible problems in making the comparison between a provision of State law and the federal regulations.

ii. What is a ''State law''?

It is unclear what the term ''provision of State law'' in sections 1178 and 264(c) means. The question is whether the provision in question must, in order to be considered to have preemptive effect, be legislatively enacted or whether administratively adopted or judicially decided State requirements must also be considered. Congress explicitly addressed the same issue in a different part of HIPAA, section 102. Section 102 enacted section 2723 of the Public Health Service Act, which is a preemption provision that applies to issuers of health insurance to ERISA plans. Section 2723 contains in subsection (d)(1) the following definition of ''State law'': ''The term [59996 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules] ''State law'' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States. By contrast, Congress provided no definition of the term ''State law'' in section 264. This omission suggests two policy options. One is to adopt the above definition, as a reasonable definition of the term and as an indication of what Congress probably intended in the preemption context (the policy embodied in section 2723 is analogous to that embodied in section 264(c)(2), in the sense that the State laws that are not preempted are ones that provide protections to

individuals that go above and beyond the federal requirements). The other option is to argue by negative implication that, since Congress could have but did not enact the above definition in connection with sections 264 and 1178, it intended that a different definition be used, and that the most reasonable alternative is to limit the State laws to be considered to those that have been legislatively enacted.

The Department does not consider the latter option to be a realistic one. It is legally questionable and is also likely to be extremely confusing and unworkable as a practical matter, as it will be difficult to divorce State ''laws'' from implementing administrative regulations or decisions or from judicial decisions. Also, much State ''privacy law''—e.g., the law concerning the physician/patient privilege—is not found in statutes, but is rather in State common law. Finally, since health care providers and others are bound by State regulations and decisions, they would most likely find a policy that drew a line based on where a legal requirement originated very confusing and unhelpful. As a result, we conclude that the language in section 102 represents a legally supportable approach that is, for practical reasons, a realistic option, and it is accordingly proposed in proposed § 160.202 below.

iii. What is a law that ''relates to the privacy of individually identifiable health information''?

The meaning of the term ''relate to'' has been extensively adjudicated in a somewhat similar context, the issue of the preemption of State laws by ERISA. Section 514(a) of ERISA (29 U.S.C. 1144(a)) provides that ERISA ''shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.'' (Emphasis added.) The U.S. Supreme Court alone has decided 17 ERISA preemption cases, and there are numerous lower court cases. The term also has been interpreted in other contexts. Thus, there would seem to be several options for defining the term ''relates to'': (1) By using the criteria developed by the Supreme Court as they evolve, (2) by using the criteria developed by the Supreme Court, but on a static basis, and (3) based on the legislative history, by setting federal criteria.

The first option would be based on the definition adopted in an early ERISA case, *Shaw v. Delta Airlines, Inc*., 463 U.S. 85 (1983), as it continues to evolve. In Shaw, a unanimous Supreme Court adopted a very broad reading of the term, holding that a law ''relates to'' an employee benefit plan ''if it has a connection with or reference to'' such a plan. Later cases have developed a more particularized and complex definition of this general definition. The Supreme Court has also applied the Shaw definition outside of the ERISA context. In

Morales v. Trans World Airlines, 504 U.S. 374 (1992), the Court defined the term ''relating to'' in the Airline Deregulation Act by using the definition of the term ''relates to'' developed under the ERISA cases above. While this option would appear to be a supportable reading of the statutory term, tying the agency interpretation to an evolving court interpretation will make it more difficult to make judgments, and particular judgments may change as the underlying court interpretations change.

The second option we considered would ''freeze'' the definition of ''relates to'' as the Court has currently defined it. This option also is a supportable reading of the statutory term, but is less of a moving target than the prior option. The complexity of the underlying court definition presents problems.

The option selected and reflected in the rules proposed below grows out of the movement in recent years of the Supreme Court away from the literal, textual approach of Shaw and related cases to an analysis that looks more at the purposes and effects of the preemption statute in question. In *New York State Conference of Blue Cross v. Travelers Insurance Co*., 514 U.S. 645 (1995), the Court held that the proper inquiry in determining whether the State law in question related to an employee benefit plan was to look to the objectives of the (ERISA) statute as a guide to the scope of the State law that Congress understood would survive. The Court drew a similar line in Morales, concluding that State actions that affected airline rates, routes, or services in ''too tenuous, remote, or peripheral a manner'' would not be preempted. 504 U.S. at 384. The Court drew a conceptually consistent line with respect to the question of the effect of a State law in English v. General Electric Co., 496 U.S. 72, 84 (1990); see also, Gade v. National Solid Wastes Management Ass'n., 505 U.S. 88 (1992). The Court held that deciding which State laws were preempted by the OSH Act required also looking at the effect of the State law in question, and that those which regulated occupational safety and health in a ''clear, direct, and substantial way'' would be preempted. These cases suggest an approach that looks to the legislative history of HIPAA and seeks to determine what kinds of State laws Congress meant, in this area, to leave intact and also seeks to apply more of a ''rule of reason'' in deciding which State laws ''relate to'' privacy and which do not.

> The legislative history of HIPAA offers some insight into the meaning of the term ''relates to.'' The House Report (House Rep. No. 496, 104th Cong., 2d Sess., at 103) states that—

> The intent of this section is to ensure that State privacy laws that are more stringent than the requirements and standards contained in the bill are not superseded.

Based on this legislative history, one could argue that the ''State laws'' covered by the ''relates to'' clause are simply those that are specifically or explicitly designed to regulate the privacy of personal health information, and not ones that might have the incidental effect of doing so. Thus, the option selected below appears to be consistent with the Court's approach in *Travelers*, and, together with the ''effect'' test, seems to be closer to how the Court is analyzing preemption issues. It makes sense on a common sense basis as well, and appears, from the little legislative history available, to be what Congress intended in this context.

iv. When is a provision of State law ''contrary'' to the analogous federal requirement?

The statute uses the same language in both section 1178(a)(1) and section 264(c)(2) to delineate the general precondition for preemption: the provision of State law must be ''contrary'' to the relevant federal requirement, standard, or implementation specification; the term ''contrary,'' however, is not defined. It should be noted that this issue (the meaning of the term ''contrary'') does not arise solely in the context of the proposed privacy standard. The term ''contrary'' appears throughout section 1178(a) and is a precondition for any preemption analysis done under that section. [59997 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules]

The definition set out at proposed § 160.202 embodies the tests that the courts have developed to analyze what is known as ''conflict preemption.'' In this analysis, the courts will consider a provision of State law to be in conflict with a provision of federal law where it would be impossible for a private party to comply with both State and federal requirements or where the provision of State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'' This latter test has been further defined as, where the State law in question ''interferes with the methods by which the federal statute was designed to reach (its) goal.'' *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). In Gade, the Supreme Court applied this latter test to preempt an Illinois law and regulations that imposed additional, non-conflicting conditions on employers, holding that the additional conditions conflicted with the underlying congressional purpose to have one set of requirements apply. This test, then, is particularly relevant with respect to the other HIPAA regulations, where Congress clearly intended uniform standards to apply nationwide.

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The Department is of the view that this definition should be workable and is probably what Congress intended in using the term—as a shorthand reference to the case law. We considered a broader definition (''inconsistent with''), but rejected it on the grounds that it would have less legal support and would be no easier to apply than the statutory term ''contrary'' itself.

v. What is the meaning of ''more stringent''?

The issue of when a provision of State law is ''more stringent'' than the comparable ''requirements, standards, or implementation specifications'' of the HIPAA privacy regulation is not an easy one. In general, it seems reasonable to assume that ''more stringent'' means ''providing greater privacy protection'' but, such an interpretation leads to somewhat different applications, depending on the context. For example, a State law that provided for fewer and more limited disclosures than the HIPAA privacy regulation would be ''more stringent.'' At the same time, a State law that provides for more and/or greater penalties for wrongful disclosures than does the HIPAA privacy regulation would also be ''more stringent.'' Thus, in the former case, ''more stringent'' means less or fewer, while in the latter case, ''more stringent'' means more or greater. In addition, some situations are more difficult to characterize. For example, if the HIPAA privacy regulation requires disclosure to the individual on request and a State law prohibits disclosure in the circumstance in question, which law is ''more stringent'' or ''provides more privacy protection'?

A continuum of regulatory options is available. At one end of the continuum is the minimalist approach of not interpreting the term ''more stringent'' further or spelling out only a general interpretation, such as the ''provides more privacy protection'' standard, and leaving the specific applications to later case-by-case determinations. At the other end of the continuum is the approach of spelling out in the regulation a number of different applications, to create a very specific analytic framework for future determinations. We propose below the latter approach for several reasons: specific criteria will simplify the determination process for agency officials, as some determinations will be already covered by the regulation, while others will be obvious; specific criteria will also provide guidance for determinations where issue of ''stringency'' is not obvious; courts will be more likely to give deference to agency determinations, leading to greater uniformity and consistency of expectation; and the public, regulated entities, and States will have more notice as to what the determinations are likely to be.

The specific criteria proposed at proposed § 160.202 are extrapolated from the principles of the fair information practices that underlie and inform these

proposed rules and the Secretary's Recommendations. For example, limiting disclosure of personal health information obviously protects privacy; thus, under the criteria proposed below, the law providing for less disclosure is considered to be ''more stringent.'' Similarly, as the access of an individual to his or her protected health information is considered to be central to enabling the individual to protect such information, the criteria proposed below treat a law granting greater rights of access as ''more stringent.'' We recognize that many State laws require patients to authorize or consent to disclosures of their health information for treatment and/or payment purposes. We consider individual authorization generally to be more protective of privacy interests than the lack of such authorization, so such State requirements would generally stand, under the definition proposed below.

However, we would interpret a State law relating to individual authorization to be preempted if the law requires, or would permit a provider or health plan to require, as a condition of treatment or payment for health care, an individual to authorize uses or disclosures for purposes other than treatment, payment and health care operations, and if such authorization would override restrictions or limitations in this regulation relating to the uses and disclosures for purposes other than treatment, payment and health care operations. For example, if a State law permitted or required a provider to obtain an individual authorization for disclosure as a condition of treatment, and further permitted the provider to include in the authorization disclosures for research or for commercial purposes, the State law would be preempted with respect to the compelled authorization for research or commercial purposes. At the same time, if a State law required a provider to obtain an individual authorization for disclosure as a condition of treatment, and further required the provider to include an authorization for the provider to disclosure data to a State data reporting agency, such a law would not be preempted, because State laws that require such data reporting are saved from preemption under section § 1178(c) of the statute.

In addition, to the extent that a State consent law does not contain other consent or authorization requirements that parallel or are stricter than the applicable federal requirements, those detailed federal requirements would also continue to apply. We solicit comment in particular on how these proposed criteria would be likely to operate with respect to particular State privacy laws.

e. The process for making administrative determinations regarding the preemption of State health information privacy laws.

Because States generally have laws that relate to the privacy of individually identifiable health information, there may be conflicts between provisions of

various State laws and the federal requirements. Where such conflicts appear to exist, questions may arise from the regulated entities or from the public concerning which requirements apply. It is possible that such questions may also arise in the context of the Secretary's enforcement of the civil monetary penalty provisions of section 1176. The Secretary accordingly proposes to adopt the following process for responding to such comments and making the determinations necessary to carry out her responsibilities under section 1176.

The rules proposed below would establish two related processes: one for making the determinations called for by [59998 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules]section 1178(a)(2)(A) of the Act and the other for issuing advisory opinions regarding whether a provision of State law would come within the exception provided for by section 1178(a)(2)(B).

i. Determinations under section 1178(a)(2)(A).

The rules proposed below should not usually implicate section 1178(a)(2)(A), which provides that a State law will not be preempted where the Secretary determines it is necessary for one or more of five specific purposes: (1) To prevent fraud and abuse; (2) to ensure appropriate State regulation of insurance and health plans; (3) for State reporting on health care delivery or costs; (4) for other purposes; or (5) which address controlled substances. The process for implementing this statutory provision is proposed here, because the issue of how such preemption issues will be handled has been raised in prior HIPAA rulemakings and needs to be addressed, and, as explained above, the statutory provision itself is fairly intertwined (in terms of the specific terms used), with the preemption provisions of the statute that relate to privacy.

The process proposed below for determinations by the Secretary would permit States to request an exception to the general rule of preemption. The decision to limit, at least as an initial matter, the right to request such determinations to States was made for several reasons. First, States are obviously most directly concerned by preemption, in that it is State legislative, judicial, or executive action that the federal requirements supersede. Principles of comity dictate that States be given the opportunity to make the case that their laws should not be superseded. Second, States are in the best position to address the issue of how their laws operate and what their intent is, both of which are relevant to the determination to be made. Third, we need to control the process as an initial matter, so that the Secretary is not overwhelmed by requests. Fourth, where particular federal requirements will have a major impact on providers, plans, or clearinghouses within a particular State, we assume that they will be able to work with their State governments to raise the issue with the Secretary; the discussion

process that such negotiations should entail should help crystallize the legal and other issues for the Secretary and, hence, result in better determinations. We emphasize that HHS may well revisit this issue, once it has gained some experience with the proposed process.

Proposed § 160.204(a)(1) sets out a number of requirements for requests for determinations. In general, the purpose of these requirements is to provide as complete a statement as possible of the relevant information as an initial matter, to minimize the time needed for the Secretarial determination.

The remaining requirements of proposed § 160.204(a) generally are designed to set out an orderly process and effect of the determinations. Of particular note is proposed § 160.204(a)(5), which provides that such determinations apply only to transactions that are wholly intrastate. We recognize that in today's economy, many, perhaps most, transactions will be interstate, so that the effect of a positive determination could be minimal under this provision. Nonetheless, we think that there is no practical alternative to the proposed policy. We do not see how it would be practical to split up transactions that involved more than one State, when one State's law was preempted and the other's was not. We do not see why the non-preempted law should govern the transaction, to the extent it involved an entity in a State whose law was preempted. Quite aside from the sovereignty issues such a result would raise, such a result would be very confusing for the health care industry and others working with it and thus inconsistent with the underlying goal of administrative simplification. Rather, such a situation would seem to be a classic case for application of federal standards, and proposed § 160.204(a)(5) would accordingly provide for this.

ii. Advisory opinions under section 1178(a)(2)(B).

The rules proposed below lay out a similar process for advisory opinions under section 1178(a)(2)(B). That section of the statute provides that, subject to the requirements of section 264(c)(2) (the provision of HIPAA that establishes the ''more stringent'' preemption test), State laws that ''relate to the privacy of individually identifiable health information'' are excepted from the general rule that the HIPAA standards, requirements, and implementation specifications preempt contrary State law.

Unlike section 1178(a)(2)(A), section 1178(a)(2)(B) does not provide for the making of a determination by the Secretary. Nonetheless, it is clear that the Secretary may make judgments about the legal effect of particular State privacy laws in making compliance and enforcement decisions. It is also foreseeable that the Secretary will be asked to take a position on whether particular State privacy

laws are preempted or not. We have concluded that the best way of addressing these concerns is to provide a mechanism by which the Secretary can issue advisory opinions, so that the public may be informed about preemption judgments the Secretary has made. See proposed § 160.204(b).

The process proposed below for requesting advisory opinions is limited to States, for the reasons described in the preceding section. The requirements for requests for advisory opinions are similar to the requirements for determinations in proposed § 160.204(a), but are tailored to the different statutory requirements of sections 1178(a)(2)(A) and 264(c)(2). As with proposed § 164.204(a), the process proposed below would provide for publication of advisory opinions issued by the Secretary on an annual basis, to ensure that the public is informed of the decisions made in this area.

f. Carve-out for State public health laws.

Section 1178(b) provides that ''Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.'' This section appears to carve out an area over which the States have traditionally exercised oversight and authority—the collection of vital statistics, the enforcement of laws regarding child abuse and neglect, and the conduct of public health surveillance, investigation, and intervention. State laws in these areas may involve reporting of individually identifiable health information to State or local authorities. Section 1178(b) indicates that existing or future State laws in these areas are enforceable, notwithstanding any privacy requirements adopted pursuant to section 264(c). In addition, covered entities should not be inhibited from complying with requests authorized by State law for release of information by public health authorities for the stated purposes.

It should be noted that the limitation of section 1178(b) applies to the ''authority, power, or procedures established under any law.'' Public health laws often convey broad general authorities for the designated agency to protect public health, including enforcement powers, and these State authorities and powers would remain enforceable. Further, section 1178(b) also covers ''procedures'' authorized by law; we read this language as including State administrative regulations and guidelines.

The proposed rules propose to address these concerns by treating the [59999 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules] disclosures covered by section 1178(b) as allowable disclosures for public

health activities under proposed § 164.510(b). Thus, those disclosures permitted under proposed § 164.510(b) are intended to be, with respect to disclosures authorized by State law, at least as broad as section 1178(b). This means that disclosures that are authorized by State law but which do not come within the scope of proposed § 164.510(b) are considered to fall outside of the limitation of section 1178(b). In addition, since similar activities and information gathering are conducted by the federal government, disclosures to public health authorities authorized by federal law would be permitted disclosures under this proposed rule and applicable federal law will govern the use and redisclosure of the information.

g. Carve-out for State laws relating to oversight of health plans.

Section 1178(c) provides that nothing in part C of title XI limits the ability of States to require health plans ''to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.'' This section thus also carves out an area in which the States have traditionally regulated health care as an area which the statute intends to leave in place. State laws requiring the reporting of or access to information of the type covered by section 1178(c) will in certain cases involve the reporting of, or access to, individually identifiable health information. Accordingly, provision has been made for such reporting and access by making such reporting and access permitted disclosures and uses under this proposed rule. See proposed § 164.510(c).

2. Relationship to Other Federal Laws

The rules proposed below also would affect various federal programs, some of which may have requirements that are, or appear to be, inconsistent with the requirements proposed below. Such federal programs include those programs that are operated directly by the federal government, such as the health benefit programs for federal employees or the health programs for military personnel. They also include a wide variety of health services or benefit programs in which health services or benefits are provided by the private sector or by State or local government, but which are governed by various federal laws. Examples of the latter types of programs would be the Medicare and Medicaid programs, the health plans governed by the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001, et seq. (ERISA), the various clinical services programs funded by federal grants, and substance abuse treatment programs.

Some of the above programs are explicitly covered by HIPAA. Section 1171 of the Act defines the term ''health plan'' to include the following federally

conducted, regulated, or funded programs: group plans under ERISA which either have 50 or more participants or are administered by an entity other than the employer who established and maintains the plan; federally qualified health maintenance organizations; Medicare; Medicaid; Medicare supplemental policies; the health care program for active military personnel; the health care program for veterans; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Indian health service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.; and the Federal Employees Health Benefits Program. There also are many other federally conducted, regulated, or funded programs in which individually identifiable health information is created or maintained, but which do not come within the statutory definition of ''health plan.'' While these latter types of federally conducted, regulated, or assisted programs are not explicitly covered by part C of title XI in the same way that the programs listed in the statutory definition of ''health plan'' are covered, the statute may nonetheless apply to transactions and other activities conducted under such programs. This is likely to be the case where the federal entity or federally regulated or funded entity provides health services; the requirements of part c are likely to apply to such an entity as a ''health care provider.'' Thus, the issue of how different federal requirements apply is likely to arise in numerous contexts.

When two federal statutes appear to conflict, the courts generally engage in what is called an ''implied repeal'' analysis. The first step in such an analysis is to look for some way in which to reconcile the apparently conflicting requirements. Only if the conflicting provisions cannot be reconciled do courts reach the second step of the analysis, in which they look to see whether the later statute repealed the prior statute (to the extent of the conflict) by implication. In making such a determination, the courts look to the later statute and its legislative history, to see if there is evidence as to whether Congress intended to leave the prior statute in place or whether it intended the later statute to supersede the prior statute, to the extent of the conflict between the two. It is not a foregone conclusion that a later statute will repeal inconsistent provisions of a prior statute. Rather, there are cases in which the courts have held prior, more specific statutes not to be impliedly repealed by later, more general statutes.

As noted above, the section 1171 of the Act explicitly makes certain federal programs subject to the standards and implementation specifications promulgated by the Secretary, while entities carrying out others are implicitly covered by the scope of the term ''health care provider.'' The legislative history of the statute is silent with respect to how these requirements were to operate in the federal sector visa`- vis these and other federal programs with potentially conflicting requirements. Congress is presumed to have been aware that various federal programs that the privacy and other standards would reach would be

governed by other federal requirements, so the silence of the legislative history and the limited reach of the statute would seem to be significant. On the other hand, Congress' express inclusion of certain federal programs in the statute also has significance, as it constitutes an express Congressional statement that the HIPAA standards and implementation specifications apply to these programs. In light of the absence of relevant legislative history, we do not consider this Congressional statement strong enough to support a conclusion of implied repeal, where the conflict is one between the HIPAA regulatory standards and implementation specifications and another federal statute. However, it seems strong enough to support an inference that, with respect to these programs, the HIPAA standards and implementation specifications establish the federal policy in the case of a conflict at the regulatory level.

Thus, the first principle that applies where both the HIPAA standards and implementation specifications and the requirements of another federal program apply is that we must seek to reconcile and accommodate any apparently conflicting federal requirements. Two conclusions flow from this principle. First, where one federal statute or regulation permits an activity that another federal statute or regulation requires, and both statutes apply to the entity in question, there is no conflict, because it is possible to comply with both sets of federal requirements. [60000 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules]

Second, where one federal statute or regulation permits, but does not require, an activity that another federal statute or regulation prohibits, there is again no conflict, because it is possible to comply with both sets of federal requirements. In each case, the entity has lost some discretion that it would otherwise have had under the more permissive set of requirements, but in neither case has it been required to do something that is illegal under either federal program.

There will, however, also be cases where the privacy or other Administrative Simplification standards and implementation specifications cannot be reconciled with the requirements of another federal program. In such a case the issue of implied repeal is presented. As suggested above, we think that where the conflict is between the privacy or other Administrative simplification regulations and another federal statute, the regulatory requirements would give way, because there is insufficient evidence to support a finding that part C of title XI is intended to repeal other federal laws. For example, if other law prohibits the dissemination of classified or other sensitive information, this rule's requirements for granting individuals' right to copy their own records would give way. Where the conflict is between the Administrative Simplification regulatory requirements and other federal regulatory requirements that are discretionary (not mandated by the other

federal law), we think that there is also insufficient evidence to support a finding of implied repeal of the latter regulatory requirements, where the other federal program at issue is not one specifically addressed in section 1171. However, where the other federal program at issue is one of the ones which Congress explicitly intended to have the Administrative Simplification standards and implementation specifications apply to, by including them in the definition of ''health plan'' in section 1171, we think that there is evidence that the Administrative Simplification standards and implementation specifications should prevail over contrary exercises of discretion under those programs.

We considered whether the preemption provision of section 264(c)(2) of Public Law 104–191, discussed in the preceding section, would give effect to State laws that would otherwise be preempted by federal law. For example, we considered whether section 264(c)(2) could be read to make the Medicare program subject to State laws relating to information disclosures that are more stringent than the requirements proposed in this rule, where such laws are presently preempted by the Medicare statute. We also considered whether section 264(c)(2) could be read to apply such State laws to procedures and activities of federal agencies, such as administrative subpoenas and summons, that are prescribed under the authority of federal law. In general, we do not think that section 264(c)(2) would work to apply State law provisions to federal programs or activities with respect to which the State law provisions do not presently apply. Rather, the effect of section 264(c)(2) is to give preemptive effect to State laws that would otherwise be in effect, to the extent they conflict with and are more stringent than the requirements promulgated under the Administrative Simplification authority of HIPAA. Thus, we do not believe that it is the intent of section 264(c)(2) to give an effect to State law that it would not otherwise have in the absence of section 264(c)(2).

We explore some ramifications of these conclusions with respect to specific federal programs below. We note that the summaries below do not identify all possible conflicts or overlaps of the proposed rules with other federal requirements; rather, we have attempted to explain the general nature of the relationship of the different federal programs. We would anticipate issuing more detailed guidance in the future, when the final privacy policies are adopted, and the extent of conflict or overlap can be ascertained. We also invite comment with respect to issues raised by other federal programs.

a. The Privacy Act. The Privacy Act of 1974, 5 U.S.C. 552a, is not preempted or amended by part C of title XI.

The Privacy Act applies to all federal agencies, and to certain federal contractors who operate Privacy Act protected systems of records on behalf of federal agencies. It does not, however, apply to non-federal entities that are reached by part C. While the proposed rules are applicable to federal and nonfederal entities, they are not intended to create any conflict with Privacy Act requirements. In any situation where compliance with the proposed rules would lead a federal entity to a result contrary to the Privacy Act, the Privacy Act controls. In sections of the proposed rules which might otherwise create the appearance of a conflict with Privacy Act requirements, entities subject to the Privacy Act are directed to continue to comply with Privacy Act requirements.

Because the Privacy Act gives federal agencies the authority to promulgate agency-specific implementing regulations, and because the Privacy Act also allows agencies to publish routine uses that have the status of exceptions to the Privacy Act's general rule prohibiting disclosure of Privacy Act protected information to third parties, the issue of possible conflicts between the proposed Administrative Simplification rules and existing Privacy Act rules and routine uses must be addressed. Where the federal program at issue is one of the ones that Congress explicitly intended to have the Administrative Simplification standards and implementation specifications apply to, by including them in the definition of ''health plan'' in section 1171, we think that there is evidence that the Administrative Simplification standards and implementation specifications should prevail over contrary exercises of discretion under those programs. That is, to the extent that a routine use is truly discretionary to an agency which is also a covered entity under section 1172(a), the agency would not have discretion to ignore the Administrative Simplification regulations. It is possible, however, that in some cases there might be underlying federal statutes that call for disclosure of certain types of information, and routine uses could be promulgated as the only way to implement those statutes and still comply with the Privacy Act. If this were to happen or be the case, the routine use should prevail.

b. The Substance Abuse Confidentiality regulations.

Regulations that are codified at 42 CFR part 2 establish confidentiality requirements for the patient records of substance abuse ''programs'' that are ''federally assisted.'' Substance abuse programs are specialized programs or personnel that provide alcohol and drug abuse treatment, diagnosis, or referral for treatment. 42 CFR 2.11. The term ''federally assisted'' is broadly defined, and includes federal tax exempt status and Medicare certification, among other criteria. 42 CFR 2.12(b). Such programs may not disclose patient identifying information without the written consent of the patient, unless the information is needed to respond to a medical emergency, or such information is disclosed for

purposes of research, audit, or evaluation. Disclosures may not be made in response to a subpoena; rather, a court order is required in order for a disclosure of covered records to be lawfully made. Limited disclosures may also be made by such programs to State or local officials under a State law requiring reporting of incidents of suspected child abuse and neglect and [60001 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules]

to law enforcement officials regarding a patient's crime on program premises or against program personnel or a threat to commit such a crime. 42 CFR 2.12. Unlike the rules proposed below, the confidentiality protections continue indefinitely after death, although part 2 would permit disclosure of identifying information relating to the cause of death under laws relating to the collection of vital statistics or permitting inquiry into cause of death.

It seems likely that most, if not all, programs covered by the part 2 regulations will also be covered, as health care providers, by the rules proposed below. As can be seen from the above summary, the part 2 regulations would not permit many disclosures that would be permitted under proposed § 164.510 below, such as many disclosures for law enforcement, directory information, governmental health data systems, and judicial and other purposes. In addition, the general permissive disclosure for treatment or payment purposes at proposed § 164.506 below would be inconsistent with the more restrictive requirements at part 2. In such situations, providers (or others) subject to both sets of requirements could not make disclosures prohibited by part 2, even if the same disclosures would be permitted under the rules proposed below.

There are also a number of requirements of the part 2 regulations that parallel the requirements proposed below. For example, the minimum necessary rule, where applicable, would parallel a similar requirement at 42 CFR 2.13(a). Similarly, the notice requirements of part 2, at 42 CFR 2.22 parallel the notice requirements proposed below, although the notice required below would be more detailed and cover more issues. The preemptive effect on State law should be the same under both part 2 and section 264(c)(2). The requirements for disclosures for research proposed below are likewise similar to those in part 2. In such cases, health care providers would have to comply with the more extensive or detailed requirements, but there should be no direct conflict.

Many other provisions of the proposed rules, however, simply have no counterpart in part 2. For example, the part 2 regulations do not require programs to maintain an accounting of uses and disclosures, nor do they provide for a right to request amendment or correction of patient information. Similarly, the part 2 regulations contain no prohibition on conditioning treatment or payment on

provision of an individual authorization for disclosure. In such situations, health care providers would be bound by both sets of requirements.

c. ERISA.

ERISA was enacted in 1974 to regulate pension and welfare employee benefit plans that are established by private sector employers, unions, or both, to provide benefits to their workers and dependents. An employee welfare benefit plan includes plans that provide ''through the purchase of insurance or otherwise * * * medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, (or) death.'' 29 U.S.C. 1002(1). In 1996, Public Law 104–191 amended ERISA to require portability, nondiscrimination, and renewability of health benefits provided by group health plans and group health insurance issuers. Numerous, although not all, ERISA plans are covered under the rules proposed below as ''health plans.''

As noted above, section 514(a) of ERISA, 29 U.S.C. 1144(a), preempts all State laws that ''relate to'' any employee benefit plan. However, section 514(b) of ERISA, 29 U.S.C. 1144(b)(2)(A), expressly saves from preemption State laws which regulate insurance. Section of ERISA, 29 U.S.C. 1144(b)(2)(B), provides that an ERISA plan is deemed not to be an insurer for the purpose of regulating the plan under the State insurance laws. Thus, under the deemer clause, States may not treat ERISA plans as insurers subject to direct regulation by State law. Finally, section 514(d) of ERISA, 29 U.S.C. 1144(d), provides that ERISA does not ''alter, amend, modify, invalidate, impair, or supersede any law of the United States.''

We considered whether the preemption provision of section 264(c)(2) of Public Law 104–191, discussed in the preceding section, would give effect to State laws that would otherwise be preempted by section 514(a) of ERISA. Our reading of the statutes together is that the effect of section 264(c)(2) is simply to leave in place State privacy protections that would otherwise apply and which are more stringent than the federal privacy protections. In the case of ERISA plans, however, if those laws are preempted by section 514(a), they would not otherwise apply. We do not think that it is the intent of section 264(c)(2) to give an effect to State law that it would not otherwise have in the absence of section 264(c)(2). Thus, we would not view the preemption provisions below as applying to State laws otherwise preempted by section 514(a) of ERISA.

Many plans covered by the rules proposed below are also subject to ERISA requirements. To date our discussions and consultations have not uncovered any particular ERISA requirements that would conflict with the rules proposed below.

However, we invite comment, particularly in the form of specific identification of statutory or regulatory provisions, of requirements under ERISA that would appear to conflict with provisions of the rules proposed below.

d. Other federally funded health programs.

There are a number of authorities under the Public Health Service Act and other legislation that contain explicit confidentiality requirements either in the enabling legislation or in the implementing regulations. Many of these are so general that there would appear to be no problem of inconsistency, in that nothing in the legislation or regulations would appear to restrict the assisted provider's discretion to comply with the requirements proposed below. There are, however, several authorities under which either the requirements of the enabling legislation or of the program regulations would impose requirements that would differ from the rules proposed below. We have identified several as presenting potential issues in this regard. First, regulations applicable to the substance abuse block grant program funded under section 1943(b) of the Public Health Service Act require compliance with 42 CFR part 2, and thus raise the issues identified in section 2 above. Second, there are a number of federal programs which, either by statute or by regulation, restrict the disclosure of patient information to, with minor exceptions, disclosures ''required by law.'' See, for example, the program of projects for prevention and control of sexually transmitted diseases funded under section 318(e)(5) of the Public Health Service Act (42 CFR 51b.404); the regulations implementing the community health center program funded under section 330 of the Public Health Service Act (42 CFR 51c.110); the regulations implementing the program of grants for family planning services under title X of the Public Health Service Act (42 CFR 59.15); the regulations implementing the program of grants for black lung clinics funded under 30 U.S.C. 437(a) (42 CFR 55a.104); the regulations implementing the program of maternal and child health projects funded under section 501 of the Act (42 CFR 51a.6); the regulations implementing the program of medical examinations of coal miners (42 CFR 37.80(a)). These legal requirements would restrict the grantees or other entities under the programs [60002 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules] involved from making many of the disclosures that proposed § 164.510 would permit. In some cases, permissive disclosures for treatment, payment or health care operations would also be limited. Since proposed § 164.510 is merely permissive, there would not be a conflict between the program requirements, as it would be possible to comply with both. However, it should be recognized that entities subject to both sets of requirements would not have the total range of discretion that the rules proposed below would suggest. [60002 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Proposed Rules]

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IV. Preliminary Regulatory Impact Analysis

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Establishing minimum standards for health care privacy protection is an attempt to create a baseline level of privacy protection for patients across States. The Health Privacy Project's report, *The State of Health Privacy: An Uneven Terrain* 6 [fn6 Janlori Goldman, Institute for Health Care Research and Policy, Georgetown University: www.healthprivacy.org/resources.] makes it clear that under the current system of state laws, privacy protection is extremely variable. Our statutory authority under HIPAA allows us to preempt state laws when state law provides less stringent privacy protection than the regulation. Only in cases where state law does not protect the patient's health information as stringently as in this proposed rule, or when state law is more restrictive of a patient's right to access their own health care information, will our rule preempt state law. We discuss preemption in greater detail in other parts of the preamble (see the effects of the rule on state laws, section 2 below). [60005 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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2. State Laws

The second body of privacy protections is found in a myriad of State laws and requirements. To determine whether or not the proposed rule would preempt a State law, we first identified the relevant laws, and second, determined whether state or federal law provides individuals with greater privacy protection.

Identifying the relevant state statutes: Health privacy statutes can be found in laws applicable to many issues including insurance, worker's compensation, public health, birth and death records, adoptions, education, and welfare. For example, Florida has over 60 laws that apply to protected health information. According to the Georgetown Privacy Project 11 [fn11 *Ibid*, Goldman, p. 6], Florida is not unique. Every State has laws and regulations covering some aspect of medical information privacy. In many cases, State laws were enacted to address a specific situation, such as the reporting of HIV/AIDS, or medical conditions that would impair a person's ability to drive a car. Identifying every State statute, regulation, and court case that interprets statutes and regulations dealing with patient medical privacy dealing with patient medical privacy rights is an important task but cannot be completed in this discussion. For the purpose of this analysis, we simply acknowledge the complexity of State requirements surrounding privacy issues.

Lastly, we recognize that the private sector will need to complete a State-by-State analysis to comply with the notice and administrative procedures portion of this proposed rule. This comparison should be completed in the context of individual markets; therefore it is more efficient for professional associations or individual businesses to complete this task.

Recognizing limits of our ability to effectively summarize State privacy laws and our difficulty in determining preemption at the outset, we discuss conclusions generated by the Georgetown University Privacy Project in Janlori Goldman's report, *The State of Health Privacy: An Uneven Terrain*. We consider Georgetown's report the best and most comprehensive examination of State privacy laws currently published. The report, which was completed in July 1999, is based on a 50-state survey. However, the author is quick to point out that this study is not exhaustive.

The following analysis of State privacy statutes and our attempt to compare State laws to the proposed rule is limited as a result of the large amount of State-specific data available. To facilitate discussion, we have organized the analysis into two sections: access to medical information and disclosure of medical information. Our analysis is intended to suggest areas where the proposed rule appears to preempt various State laws; it is not designed to be a definitive or wholly comprehensive State-by-State comparison.

Access to Subject's Information: In general, State statutes provide individuals with access to their own medical records. However, only a few States allow individuals access to virtually all entities that hold health information. In 33 States, individuals may access their hospital and health facility records. Only 13 States guarantee individuals access to their HMO records, and 16 States provide individuals access to their medical information when it is held by insurers. Seven states have no statutory right of patient access; three States and the District of Columbia have laws that only assure individuals' right to access their mental health records. Only one State permits individuals access to records held by providers, but it excludes pharmacists from the definition of provider. Thirteen States grant individuals statutory right of access to pharmacy records. [60011 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations.]

The amount that entities are allowed to charge for copying of individuals' records varies widely from State to State. A study conducted by the American Health Information Management Association 12 [fn12 ''Practice Briefs,'' Journal of AHIMA; Harry Rhodes, Joan C. Larson, Association of Health Information Outsourcing Service; January 1999] found considerable variation in the amounts,

structure, and combination of fees for search and retrieval, and the copying of the record.

In 35 States, there are laws or regulations that set a basis for charging individuals inspecting and copying fees. Charges vary not only by State, but also by whether the request is related to a worker's compensation case or a patient-initiated request. Charges also vary according to the setting. For example, States differentiate most often between clinics and hospitals. Also, charges vary by the number of pages and whether the request is for X-rays or for standard medical information.

Of the 35 States with laws regulating inspection and copying charges, seven States either do not allow charges for retrieval of records or require that the entity provide the first copy free of charge. Some States may prohibit hospitals from charging patients a retrieval and copying fee, but allow clinics to do so. It is noteworthy that some States that do not permit charges for retrieval sometimes allow entities to charge per-page rates ranging between $0.50 and $0.75. In States that do allow a retrieval charge, the per-page charge is usually $0.25. Eleven states specify only that the record holder may charge ''reasonable/actual costs.''

Of the States that allow entities to charge for record retrieval and copying, charges range from a flat amount of $1.00 to $20.00. Other States allow entities to charge varying rates depending on the amount of material copied. For example, an entity may charge $5.00 for the first five pages and then a fixed amount per page. In those cases, it appears that retrieval and copying costs were actually combined. The remaining States have a variety of cost structures: One State allows $0.25 per page plus postage plus a $15.00 retrieval charge. Another State allows a $1.00 charge per page for the first 25 pages and $0.25 for each page above 25 pages plus a $1.00 annual retrieval charge. A third state allows a $1.00 per page charge for the first 100 pages and $0.25 for each page thereafter.

According to the report by the Georgetown Privacy Project, among States that do grant access to patient records, the most common basis for denying individuals access is concern for the life and safety of the individual or others. This proposed rule considers the question of whether to deny patient access on the basis of concern for the individual's life or safety, concluding that the benefits of patient access most often outweigh harm to the individual. This issue, which is discussed in greater detail in other sections, has been resolved in favor of promoting patient access.

The amount of time an entity is given to supply the individual with his or her record varies widely. Many States allow individuals to amend or correct inaccurate health information, especially information held by insurers. However, few States provide the right to insert a statement in the record challenging the covered entity's information when the individual and entity disagree.13 [fn13 *Ibid*, Goldman, p.20.]

Disclosure of Health Information: State laws vary widely with respect to disclosure of identifiable health information. Generally, States have applied restrictions on the disclosure of health information either to specific entities or to specific health conditions. Just two states place broad limits on disclosure of protected health information without regard for policies and procedures developed by covered entities. Most States require patient authorization before an entity may disclose health information, but as the Georgetown report points out, ''In effect, the authorization may function more as a waiver of consent—the patient may not have an opportunity to object to any disclosures.'' 14 [fn14 *Ibid*, Goldman, p. 21.]

It is also important to point out that none of the States appear to offer individuals the right to restrict disclosure of their protected health information for treatment. Thus, the provision of the proposed rule that allows patients to restrict disclosure of the their protected information is not currently included in any State law. Because the ability to restrict disclosure currently is not a standard practice, the proposed rule would require entities to add these capabilities to their information systems.

State statutes often have exceptions to requiring authorization before disclosure. The most common exceptions are for purposes of treatment, payment, or auditing and quality assurance functions—which are similar to the definition we have established for health care operations, are therefore not subject to prior authorization requirements under the proposed rule. Restrictions on redisclosure of protected health information also vary widely from State to State. Some States restrict the redisclosure of health information, and others do not. The Georgetown report cites State laws that require providers to adhere to professional codes of conduct and ethics with respect to disclosure and re-disclosure of protected health information. What is not clear is the degree to which individual information is improperly released or used in the absence of specific legal sanctions.

Most States have adopted specific measures to provide additional protections with regard to certain conditions or illnesses that have clear social or economic consequences. Although the Georgetown study does not indicate the number of

States that have adopted disease-specific measures to protect information related to sensitive conditions and illnesses, the analysis seems to suggest that nearly all States have adopted some form of additional protection. The conditions and illnesses most commonly afforded added privacy protection are:

- Substance abuse;
- Information derived from genetic testing;
- Communicable and sexually transmitted diseases;
- Mental health; and
- Abuse, neglect, domestic violence, and sexual assault

We have included a specific discussion of disclosures for research purposes because if an entity decides to disclose information for research purposes, it will incur costs that otherwise would be associated with other disclosures under this rule. Some States place restrictions on releasing condition-specific health information for research purposes, while others allow release of information for research without the patient's authorization. States frequently require that researchers studying genetic diseases, HIV/AIDS, and other sexually transmitted diseases have different authorization and privacy controls than those used for other types of research. Some States require approval from an IRB or agreements that the data will be destroyed or identifiers removed at the earliest possible time. Another approach has been for States to require researchers to obtain sensitive, identifiable information from a State public health department. One State does not allow automatic release of protected health information for research purposes without notifying the subjects that their health information may be used in research and allowing [60013 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations] them opportunity to object to the use of their information.15 [fn15 ''Medical records and privacy: empirical effects of legislation; A memorial to Alice Hersh'; McCarthy, Douglas B; Shatin, Deborah; et al. Health Service Research: April 1, 1999; No. 1, Vol. 34; p. 417.] The article details the effects of the Minnesota law conditioning disclosure of protected health information on patient authorization.

Comparing State statutes to the proposed rule: A comparison of State privacy laws with the proposed rule highlights several of the proposed rule's key implications:

- No State law requires covered entities to make their privacy and access policies available to patients. Thus, all covered entities that have direct contact with patients will be required to prepare a statement of their privacy protection and access policies. This necessarily assumes that entities have to develop procedures if they do not already have them in place.

- . The proposed rule will affect more entities than are affected under many State laws. In the application of the proposed rule to providers, plans, and clearinghouses, the proposed rule will reach nearly all entities involved in delivering and paying for health care. Yet because HIPAA applies only to information that has been stored and transmitted electronically, the extent to which the proposed rule will reach information held by covered entities is unclear.
- State laws have not addressed the form in which health information is stored. We do not know whether covered entities will choose to treat information that never has been maintained or transmitted electronically in the same way that they treat postelectronic information. We also do not know what portion of information held in non-electronic formats has ever been electronically maintained or transmitted. Nevertheless, the proposed rule would establish a more level floor from which States could expand the privacy protections to include both electronic information and non-electronic information.
- Among the three categories of covered entities, it appears that plans will be the most significantly affected by the access provisions of the proposed rule. Based on the Health Insurance Association of America (HIAA) data,16 [fn16 *Source Book of Health Insurance Data: 1997–1998*, Health Insurance Association of America,1998. p. 33] there are approximately 94.7 million non-elderly persons who purchase health insurance in the 35 States that do not provide patients a legal right to inspect and copy their records. We do not have information on how many of those people are in plans that grant patients inspection and copying rights although State law does not require them to do so. We discuss these points more fully in the cost analysis section.
- Although the proposed rule would establish a uniform disclosure and redisclosure requirement for all covered entities, the groups most likely to be affected are health insurers, benefits management administrators, and managed care organizations. These groups have the greatest ability and economic incentives to use protected health information for marketing services to both patients and physicians without individual authorization. Under the proposed rule, covered entities would have to obtain the individual's authorization before they could use or disclose their information for purposes other than treatment, payment, and health care operations—except in the situations explicitly defined as allowable disclosures without authorization.
- . While our proposed rule appears to encompass many of the requirements found in current State laws, it also is clear that within State laws, there are many provisions that cover specific cases and health conditions. Certainly, in States that have no research disclosure requirements, the proposed

rule will establish a baseline standard. But in States that do place conditions on the disclosure of protected health information, the proposed rule may place additional requirements on covered entities.

- State privacy laws do not always apply to entities covered by the proposed rule. For example, State laws may provide strong privacy protection for hospitals and doctors but not for dentists or HMOs. State laws protecting particular types of genetic testing or conditions may be similarly problematic because they protect some types of sensitive information and not others. In some instances, a patient's right to inspect his or her medical record may be covered under State laws and regulations when a physician has the medical information, but not under State requirements when the information being sought is held by a plan. Thus, the proposed rule would extend privacy requirements already applicable to some entities within a State to other entities that currently are not subject to State privacy requirements.

3. Federal Laws

The Privacy Act of 1974. Federal agencies will be required to comply with both the Privacy Act of 1974 (5 U.S.C. 552a) and the HIPAA regulation. The Privacy Act provides Federal agencies with a framework and scheme for protecting privacy, and the HIPAA regulation will not alter that scheme. Basic organizational and management features, such as the provision of safeguards to protect the privacy of health information and training for employees—which are required by this proposed rule—already are required by the Privacy Act.

The proposed rule has been designed so that individuals will not have fewer rights than they have now under the Privacy Act. It may require that agencies obtain individual authorization for some disclosures that they now make without authorization under routine uses.

Private-sector organizations with contracts to conduct personal data handling activities for the Federal government are subject to the Privacy Act by virtue of performing a function on behalf of a Federal agency. They too will be required to comply with both rules in the same manner as Federal agencies.

Substance Abuse Confidentiality Statute. Organizations that operate specialized substance abuse treatment facilities and that either receive Federal assistance or are regulated by a Federal agency are subject to confidentiality rules established by section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) and implementing regulations at 42 CFR part 2.

These organizations will be subject both to that statute and to the HIPAA regulation. The proposed rule should have little practical effect on the disclosure policies of these organizations, because the patient confidentiality statute governing information about substance abuse is generally more restrictive than this proposed rule. These organizations will continue to be subject to current restrictions on their disclosures. The substance abuse confidentiality statute does not address patient access to records; the proposed privacy rule makes clear that patient access is allowed.

Federal agencies are subject to these requirements, and currently they administer their records under both these requirements and the Privacy Act. The Department of Veterans Affairs is subject to its own substance abuse confidentiality statute, which is identical in substance to the one of more general applicability. It also covers information about HIV infection and sickle cell anemia (38 U.S.C. 7332).

Rules Regarding Protection of Human Subjects. Health care delivered by covered entities conducting clinical trials typically are subject to both the [60014 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations] proposed rule and to Federal regulations for protection of human re search subjects (The Federal Policy for the Protection of Human Subjects, codified for the Department of Health and Human Services in Title 45 CFR part 46, and/or the Food and Drug Administration's human subject regulations for research in support of medical product applications to the Food and Drug Administration, or regulated by that agency, at 21 CFR parts 50 and 56).

Current human subjects rules impose no substantive restrictions on disclosure of patient information. Institutional review boards must consider the adequacy of confiden tiality protections for subjects, and researchers must tell subjects to what extent their confidentiality will be protected. There should be no conflict between these requirements and the proposed rules. The proposed HIPAA regulation will expand on the current human subjects requirements by requiring a more detailed description of intended use of patient information. The proposed HIPAA rule also requires additional criteria for waiver of patient authorization.

Medicaid. States may use information they obtain in the process of administering Medicaid only for the purposes of administering the program, pursuant to a State plan condition in section 1902(a)(7) of the Social Security Act, 42 U.S.C. 1396a(a)(7). The proposed HIPAA rule applies to State Medicaid programs, which under the rule are considered health plans. There will be no conflict in the substantive requirements of current rules and this proposed rule. Medicaid rules

regarding disclosure of patient information are stricter than provisions of the proposed rule; therefore, Medicaid agencies simply will continue to follow the Medicaid rules.

ERISA. ERISA (29 U.S.C. 1002) was enacted in 1974 to regulate pension and welfare employee benefit plans that are established by private-sector employers, unions, or both, to provide benefits to their workers and dependents. An employee welfare benefit plan provides benefits—through insurance or otherwise—such as medical, surgical benefits, as well as benefits to cover accidents, disability, death, or unemployment. In 1996, HIPAA amended ERISA to require portability, nondiscrimination, and renewability of health benefits provided by group health plans and group health insurance issuers. Many, although not all, ERISA plans are covered under the proposed rule as health plans. We believe that the proposed rule does not conflict with ERISA. Further discussion of ERISA can be found in the preamble for this proposed rule. [60014 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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VIII. Collection of Information Requirements

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Section 160.204 Process for Requesting Exceptions.

Section 160.204 would require States to: (1) Submit a written request, that meets the requirements of this section, to the Secretary to except a provision of State law from preemption under § 160.203; (2) submit a new request to the Secretary, should there be any changes to the standard, requirement, or implementation specification or provision of State law upon which an exception previously was granted, and (3) submit a written request for an extension of the exception prior to the end of the three-year approval period for a given exception. In addition, § 160.204 would require a State to submit a written request for an advisory opinion to the Secretary that meets the requirements of § 160.204.

The burden associated with these requirements is the time and effort necessary for a State to prepare and submit the written request for preemption or advisory opinion to HCFA for approval. On an annual basis it is estimated that it will take 10 States 16 hours each to prepare and submit a request. The total annual burden associated with this requirement is 160 hours. [60045 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations]

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IX. Executive Order 12612: Federalism

The Department has examined the effects of provisions in the proposed privacy regulation on the relationship between the Federal government and the States, as required by Executive Order 12612 on ‘‘Federalism.’’ The agency concludes that preempting State or local proposed rules that provide less stringent privacy protection requirements than Federal law is consistent with this Executive Order. Overall, the proposed rule attempts to balance both the autonomy of the States with the necessity to create a Federal benchmark to preserve the privacy of personally identifiable health information. [60048 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations.]

It is recognized that the States generally have laws that relate to the privacy of individually identifiable health information. The HIPAA statute dictates the relationship between State law and this proposed rule. Except for laws that are specifically exempted by the HIPAA statute, State laws continue to be enforceable, unless they are contrary to Part C of Title XI of the standards, requirements, or implementation specifications adopted or pursuant to subpart x. However, under section 264(c)(2), not all contrary provisions of State privacy laws are preempted; rather, the law provides that contrary provisions that are also ‘‘more stringent’’ than the federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate ‘‘where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope.’’ Personal privacy issues are widely identified as a national concern by virtue of the scope of interstate health commerce. HIPAA’s provisions reflect this position. HIPAA attempts to facilitate the electronic exchange of financial and administrative health plan transactions while recognizing challenges that local, national, and international information sharing raise to confidentiality and privacy of health information.

Section 3(d)(2) of the Executive Order 12612 requires that the Federal government refrain from ‘‘establishing uniform, national standards for programs and, when possible, defer to the States to establish standards.’’ HIPAA requires HHS to establish standards, and we have done so accordingly. This approach is a key component of the proposed privacy rule, and it adheres to Section 4(a) of Executive Order 12612, which expressly contemplates preemption when there is a conflict between exercising State and Federal authority under Federal statute. Section 262 of HIPAA enacted Section 1178 of the Social Security Act, developing a ‘‘general rule’’ that State laws or provisions that are contrary to the provisions or requirements of Part C of Title XI, or the standards or

implementation specifications adopted, or established thereunder are preempted. Several exceptions to this rule exist, each of which is designed to maintain a high degree of State autonomy.

Moreover, Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rule making context when there is ''firm and palpable evidence compelling the conclusion that the Congress intended to delegate to the * * * agency the authority to issue regulations preempting State law.'' Section 1178 (a)(2)(B) of HIPAA specifically preempts State laws related to the privacy of individually identifiable health information unless the State law is more stringent. Thus, we have interpreted State and local laws and regulations that would impose less stringent requirements for protection of individually identifiable health information as undermining the agency's goal of ensuring that all patients who receive medical services are assured a minimum level of personal privacy. Particularly where the absence of privacy protection undermines an individual's access to health care services, both the personal and public interest is served by establishing Federal rules.

The proposed rule would establish national minimum standards with respect to the collection, maintenance, access, transfer, and disclosure of personally identifiable health information. The Federal law will preempt State law only where State and Federal laws are ''contradictory'' and the Federal regulation is judged to establish ''more stringent'' privacy protections than State laws.

As required by the Executive Order, States and local governments will be given, through this notice of proposed rule making, an opportunity to participate in the proceedings to preempt State and local laws (section 4(e) of Executive Order 12612). However, it should be noted that the preemption of state law is based on the HIPAA statute. The Secretary will also provide a review of preemption issues upon requests from States. In addition, under the Order, appropriate officials and organizations will be consulted before this proposed action is implemented (section 3(a) of Executive Order 12612).

Finally, we have considered the cost burden that this proposed rule would impose on State-operated health care entities, Medicaid, and other State health benefits programs. We do not have access to reliable information on the number of State-operated entities and programs, nor do we have access to data on the costs these entities and programs would incur in order to comply with the proposed rule. A discussion of possible compliance costs that covered entities may incur is contained in the Unfunded Mandates section above. We believe that requiring State health care entities covered by the proposed rule to comply with the proposed rule would cost less than one percent of a State's annual budget.

The agency concludes that the policy proposed in this document has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; that this policy is not inconsistent with that Order; that this policy will not impose significant additional costs and burdens on the States; and that this policy will not affect the ability of the States to discharge traditional State governmental functions.

During our consultation with the States, representatives from various State agencies and offices expressed concern that the proposed regulation would pre-empt all State privacy laws. As explained in this section, the regulation would only pre-empt state laws where there is a direct conflict between state laws and the regulation, and where the regulation provides more stringent privacy protection than State law. We discussed this issue during our consultation with State representatives, who generally accepted our approach to the preemption issue. During the consultation, we requested further information from the States about whether they currently have laws requiring that providers have a ''duty to warn'' family members or third parties about a patient's condition other than in emergency circumstances. Since the consultation, we have not received additional comments or questions from the States. [60048 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations.]

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Note to reader: This proposed rule is one of several proposed rules that are being published to implement the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996. We propose to establish a new 45 CFR subchapter C, parts 160 through 164. Part 160 will consist of general provisions, part 162 will consists of the various Administrative Simplification regulations relating to transactions and identifiers, and part 164 will consists of the regulations implementing the security and privacy requirements of the legislation. Proposed part 160, consisting of two subparts (Subpart A General Provisions, and Subpart B—Preemption of State Law) will be exactly the same in each rule, unless we add new sections or definitions to incorporate additional general information in the later rules. [60049 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations.]

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PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

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Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart apply to determinations and advisory opinions issued by the Secretary pursuant to 42 U.S.C. 1320d–7.

1/30/2003

§ 160.202 Definitions.

For the purpose of this subpart, the following terms have the following meanings:
Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:
(1) A party would find it impossible to comply with both the State and federal requirements; or
(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104–191, as applicable.
More stringent means, in the context of a comparison of a provision of State [60051 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations] law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a law which meets one or more of the following criteria, as applicable:
(1) With respect to a use or disclosure, provides a more limited use or disclosure (in terms of the number of potential recipients of the information, the amount of information to be disclosed, or the circumstances under which information may be disclosed).
(2) With respect to the rights of individuals of access to or amendment of individually identifiable health information, permits greater rights or access or amendment, as applicable, provided, however, that nothing in this subchapter shall be construed to preempt any State law to the extent that it authorizes or prohibits disclosure of protected health information regarding a minor to a parent, guardian or person acting in loco parentis of such minor.
(3) With respect to penalties, provides greater penalties.
(4) With respect to information to be provided to an individual about a proposed use, disclosure, rights, remedies, and similar issues, provides the greater amount of information.
(5) With respect to form or substance of authorizations for use or disclosure of information, provides requirements that narrow the scope or duration, increase the difficulty of obtaining, or reduce the coercive effect of the circumstances surrounding the authorization.
(6) With respect to recordkeeping or accounting requirements, provides for the retention or reporting of more detailed information or for a longer duration.
(7) With respect to any other matter, provides greater privacy protection for the individual.
Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting

the privacy of health information or the effect of affecting the privacy of health information in a direct, clear, and substantial way.
State law means a law, decision, rule, regulation, or other State action having the effect of law.

§ 160.203 General rule and exceptions.

General rule. A standard, requirement, or implementation specification adopted under or pursuant to this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except where one or more of the following conditions is met:
(a) A determination is made by the Secretary pursuant to § 160.204(a) that the provision of State law:
(1) Is necessary:
(i) To prevent fraud and abuse;
(ii) To ensure appropriate State regulation of insurance and health plans;
(iii) For State reporting on health care delivery or costs; or
(iv) For other purposes related to improving the Medicare program, the Medicaid program, or the efficiency and effectiveness of the health care system;
or
(2) Addresses controlled substances.
(b) The provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.
(c) The provision of State law, or the State established procedures, are established under a State law providing for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.
(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

§ 160.204 Process for requesting exception determinations or advisory opinions.

(a) *Determinations*. (1) A State may submit a written request to the Secretary to except a provision of State law from preemption under § 160.203(a). The request must include the following information:
(i) The State law for which the exception is requested;
(ii) The particular standard(s), requirement(s), or implementation specification(s) for which the exception is requested;

(iii) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;
(iv) How health care providers, health plans, and other entities would be affected by the exception;
(v) The length of time for which the exception would be in effect, if less than three years;
(vi) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and
(vii) Any other information the Secretary may request in order to make the determination.
(2) Requests for exception under this section must be submitted to the Secretary at an address which will be published in the Federal Register. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.
(3) The Secretary's determination under this paragraph will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met. If it is determined that the federal standard, requirement, or implementation specification accomplishes the purposes of the criterion or criteria at § 160.203(a) as well as or better than the State law for which the request is made, the request will be denied.
(4) An exception granted under this paragraph is effective for three years or for such lesser time as is specified in the determination granting the request.
(5) If an exception is granted under this paragraph, the exception has effect only with respect to transactions taking place wholly within the State for which the exception was requested.
(6) Any change to the standard, requirement, or implementation specification or provision of State law upon which an exception was granted requires a new request for an exception.
Absent such a request and a favorable determination thereon, the standard, requirement, or implementation specification remains in effect. The responsibility for recognizing the need for and making the request lies with the original requestor.
(7) The Secretary may seek changes to a standard, requirement, or implementation specification based on requested exceptions or may urge the requesting State or other organizations or persons to do so.
(8) Determinations made by the Secretary pursuant to this paragraph will be published annually in the **Federal Register**.
(b) *Advisory opinions*.—(1) The Secretary may issue advisory opinions as to whether a provision of State law constitutes an exception under § 160.203(b) to

the general rule of preemption under that section. The Secretary may issue such opinions at the request of a State or at the Secretary's own initiative.
(2) A State may submit a written request to the Secretary for an advisory opinion under this paragraph. The [60052 Federal Register / Vol. 64, No. 212 / Wednesday, November 3, 1999 / Rules and Regulations] request must include the following information:
(i) The State law for which the exception is requested;
(ii) The particular standard(s), requirement(s), or implementation specification(s) for which the exception is requested;
(iii) How health care providers, health plans, and other entities would be affected by the exception;
(iv) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets the criteria at § 160.203(b); and
(v) Any other information the Secretary may request in order to issue the advisory opinion.
(3) The requirements of paragraphs (a)(2), (a)(5)–(a)(7) of this section apply to requests for advisory opinions under this paragraph.
(4) The Secretary's decision under this paragraph will be made on the basis of the extent to which the information provided and other factors demonstrate that the criteria at § 160.203(b) are met.
(5) Advisory opinions made by the Secretary pursuant to this paragraph will be published annually in the Federal Register.